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10/625,420	07/23/2003	Nancy Auestad	6960USP1	9175

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EXAMINER	
ROYDS, LESLIE A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,420	AUESTAD ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 and 30-32 are presented for examination.

Applicant's Amendment filed December 20, 2007 has been received and entered into the present application.

Claims 1-11 and 30-32 remain pending and under examination. Claims 1, 3, 7 and 30 are amended.

Applicant's arguments, filed December 20, 2007, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement

New Matter (New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Present claim 1 is directed to a method for decreasing the appetite of an obese or overweight mammal comprising identifying an obese or overweight mammal; and enterally administering to said mammal an amount of a long chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal, wherein the polyunsaturated fatty acid has 20 or more carbon atoms, and wherein the

polyunsaturated fatty acid is administered in the form of a triacylglycerol to treat obesity or overweight in mammals that are obese or overweight.

Present claim 7 is directed to a method for decreasing the appetite of an overweight or obese mammal comprising identifying said overweight or obese mammal; and enterally administering to said mammal an amount of long chain n-3 polyunsaturated fatty acid and an amount of long chain n-6 polyunsaturated fatty acid in relative amounts effective to decrease the appetite of said mammal, wherein the polyunsaturated fatty acids independently have 20 or more carbon atoms, and wherein the polyunsaturated fatty acids are administered in the form of a triacylglycerol to treat obesity or overweight in mammals that are obese or overweight.

In particular, the specification and claims as originally filed fail to provide adequate written description for the limitation directed to the step of identifying said overweight or obese mammal to be treated (claims 1 or 7).

MPEP §2163 states, "The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test of sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir.

1983))…Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991)."

Applicant fails to direct the Examiner to the portion(s) of the instant specification that provide written support for the newly added limitation directed to the identification of an overweight or obese mammal as now claimed. Upon consideration of Applicant's full disclosure, it is noted that the instant specification fails to describe, either explicitly or implicitly, a specific step of identifying a mammal that is either overweight or obese.

As a result, Applicant's newly added limitation directed to "identifying an obese or overweight mammal" in instant claims 1 and 7 represents a clear narrowing of the subject matter both claimed and disclosed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure because the originally disclosed subject matter fails to provide any teaching or suggestion of such an identification step. It is clear, therefore, that Applicant was not in possession of the concept of administering the claimed polyunsaturated fatty acid composition to a mammal, wherein the mammal was specifically identified prior to administration of the instantly claimed composition as being overweight or obese.

Note also that the administration of the instantly claimed polyunsaturated fatty acid composition to an overweight or obese mammal does not necessarily imply that such an overweight or obese mammal was, in fact, particularly identified as such prior to administration. In other words, it is understood that the "identification" step as claimed would include, for lack of a specific definition by Applicant, physiologic tests and/or measurements of height and weight to determine, e.g., body mass index, percentage body fat, etc. However, such a step of identifying a patient of this type is not necessarily implied since it would be possible to administer the claimed composition to a previously identified or

overtly obvious overweight or obese patient without performing the step as instantly claimed. For these reasons, and in view of the lack of a specific teaching, suggestion or disclosure as to the identification of an overweight or obese mammal prior to administration of the instantly claimed polyunsaturated fatty acid composition, Applicant's newly added limitation directed to the identification of an overweight or obese mammal is not adequately supported, either explicitly or implicitly, by the specification and claims as originally filed.

As stated in MPEP §2163, "The subject matter of the claim need not be described literally (i.e., using the same terms of *in haec verba*) in order for the disclosure to satisfy the description requirement." However, considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention, in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the limitation directed to the step of identifying said overweight or obese mammal to be treated (claims 1 or 7).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of

each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phinney et al. (WO 03/043570; Published May 2003, Priority to November 2001) in view of Visser et al. ("Elevated C-Reactive Protein Levels in Overweight and Obese Adults", *Journal of the American Medical Association*, 1999; 282:2131-2135), each already of record, for the reasons of record set forth at pages 7-11 of the previous Office Action dated June 29, 2007, of which said reasons are herein incorporated by reference.

Newly amended claim 1 remains properly included in the instant rejection because Visser et al. explicitly teaches the use of body mass index [BMI] to identify patients that are clinically overweight (BMI of 25-29.9 kg/m^2) or obese (BMI of $\geq$ 30 kg/m^2) as compared to persons of normal weight (BMI of <25 kg/m^2) and, thus, are known to demonstrate higher levels of C-reactive protein, as well as to be prone to developing diseases including, e.g., rheumatoid arthritis, diabetes mellitus and cardiovascular disease, that are associated with obesity and elevated C-reactive protein (abstract and para. bridging p.2133-2134).

One of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to use the guideline parameter of body mass index as disclosed in Visser et al. to (1) identify patients that were overweight or obese and demonstrated elevated C-reactive protein and (2) to treat those patients that are overweight or obese with the C-reactive protein biomarker reducing composition of Phinney et al., which contains a non-alpha tocopherol in combination with a highly unsaturated fatty acid, such as, *inter alia*, all-cis, 4, 7, 10, 13, 16, 19-docosahexaenoic acid (DHA) (p.1, l.4-8 and p.4, l.16-19), wherein the DHA component is administered in triglyceride form (p.11, l.30-35). Such a person would have been motivated to do so to (1) accurately identify obese patients with elevated C-reactive protein that would benefit from the CRP reducing composition of Phinney et al., (2) reduce and/or eliminate the

low-grade inflammation associated with such elevated levels of C-reactive protein and (3) reduce the risk of developing other various diseases that are known to be associated with both obesity and elevated levels of C-reactive protein, such as, e.g., rheumatoid arthritis, diabetes mellitus and cardiovascular disease. The skilled artisan would have had a reasonable expectation of success in doing so because the prior art of Visser et al. acknowledged the clear association of elevated levels of CRP with obesity and the development of other serious inflammatory disorders.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Phinney et al. fails to disclose a method of identifying an obese or overweight mammal and administering to said mammal an amount of long chain n-3 polyunsaturated fatty acid effective to decrease the appetite of said mammal. Further, Applicant submits that, while Visser et al. may disclose a correlation between elevated C-reactive protein and obese humans, nowhere in the reference is it taught or suggested that an obese human can be identified by finding elevated C-reactive protein levels. Still further, Applicant submits that the cited references, alone or in combination, fail to teach a method of treating obesity or overweight in mammals by administering long chain n-3 polyunsaturated fatty acids. Applicant alleges that there is no apparent reason to combine or modify the references to arrive at Applicant's claimed invention and asserts that, although there is potential overlap between the specific diseases, there is nothing in the references to teach or suggest that administering the composition of Phinney et al. will effect the treatment of obesity or overweight.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, in response to Applicant's argument that the cited references, either alone or in combination, fail to teach a method of treating obesity or overweight in mammals by administering long chain n-3 polyunsaturated fatty acids, it is acknowledged that the primary teachings of Phinney et al. are not explicitly directed to the appetite decreasing effects of the disclosed DHA formulation. However, the

fact remains that Phinney et al. provides a clear teaching that the disclosed formulation of a non-alpha tocopherol in combination with a highly unsaturated fatty acid, such as, eg., all-cis, 4, 7, 10, 13, 16, 19-docosahexaenoic acid (DHA) is, in fact, effective for treating all human subjects exhibiting high levels of C-reactive protein and conditions that are characterized by elevation of C-reactive protein, in order to effect a reduction in the levels of C-reactive protein, i.e., 100% of patients with elevated C-reactive protein, without exclusion. Of this entire population of patients suffering from high levels of C-reactive protein, as well as the disease states that result from elevated C-reactive protein, Visser et al. provides the factual extrinsic evidence demonstrating that a subpopulation of such patients suffering from high levels of C-reactive protein also suffer concomitantly from obesity. Accordingly, the suggestion of Phinney et al. to use the disclosed DHA-containing formulation for treating any patient exhibiting high levels of C-reactive protein and conditions that are characterized by elevation of C-reactive protein is a clear suggestion to use it in any subpopulation of patients with elevated C-reactive protein, such as those patients also suffering from obesity, with the reasonable expectation of the same (or at least substantially similar) level of efficacy in treating this subpopulation of patients as would be expected in the treatment of patients with elevated C-reactive protein *per se*. Furthermore, since products of identical composition cannot have mutually exclusive properties when administered under identical conditions, or, as in the present case, the same host, whatever effect(s) the instantly claimed DHA composition has in decreasing the appetite of an obese or overweight mammal must reasonably be necessarily present in the method disclosed by Phinney et al. in view of Visser et al., absent factual evidence to the contrary. Please see MPEP §2112.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe includes functions that are newly cited, or is identical to a product instantly claimed. In such a situation the burden is shifted to the Applicants to "prove that subject matter to be shown in the prior art does not

possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the newly cited function at the time of invention, so long as the subject matter stated to be present in the normal and usual course of execution of the disclosed method is, indeed, reasonably expected to be present. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention"). Note that, even though *Toro* was decided in the context of inherent anticipation, considerations of inherent teachings arise both in the context of anticipation and obviousness (see, e.g., *In re Napier*, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) or *In re Grasselli*, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983) and MPEP §2112). In the instant case, though Phinney et al. may not explicitly acknowledge the appetite-decreasing effects of the disclosed DHA-containing composition, the fact remains that, for the reasons discussed *supra*, such an effect would have been reasonably expected to result in the course of executing the method of reducing C-reactive protein levels in an obese patient as suggested by Phinney et al. in view of Visser et al.

Secondly, Applicant's argument that Visser et al. may disclose a correlation between elevated C-reactive protein and obese humans but fails to suggest that the artisan could identify an obese human simply by finding C-reactive protein levels is unpersuasive. The instant claims only require that the obese or overweight mammal be identified, which is clearly met by the teachings of Visser et al., who discloses that overweight or obese mammals can be identified using body mass index [BMI] (overweight: BMI of 25-29.9 kg/m^2 and obese: BMI of $\geq$ 30 kg/m^2), and who also discloses a threshold concentration of elevated CRP (i.e., $\geq$0.22 mg/dl; p.2132, col.2) to identify, of those overweight or obese patients, those with elevated CRP levels. The instant claims fail to specify that the identification step is performed on

the basis of C-reactive protein concentration, but rather just that the obese or overweight mammal is identified. In other words, though Applicant appears to argue that Visser et al. fails to teach or suggest identifying an obese human by finding elevated C-reactive protein levels, it is noted that this feature upon which Applicant alleges is not found in the cited reference(s) is not recited in the rejected claims. Further, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Thirdly, Applicant alleges that there is no apparent reason to combine or modify the references to arrive at Applicant's claimed invention and advances the following reasons in support of this allegation: (1) Phinney et al. is directed to treating symptoms of inflammatory conditions and associated systemic inflammatory responses using compositions comprising a non-alpha tocopherol and DHA, but fails to teach the identification of an obese or overweight mammal for treating obesity or overweight by decreasing its appetite and (2) Visser et al. is directed to recognizing the correlation of elevated C-reactive protein levels in overweight and obese adults, but provides no teaching or suggestion to identify an obese or overweight mammal for treatment. These allegations however, are unpersuasive for the following reasons:

(1) As previously set forth, though it is acknowledged that Phinney et al. does not explicitly teach the reduction in appetite in an obese or overweight mammal or the identification of an overweight or obese mammal, Phinney et al. provides a clear teaching that the disclosed formulation of a non-alpha tocopherol in combination with a highly unsaturated fatty acid, such as, eg., all-cis, 4, 7, 10, 13, 16, 19-docosahexaenoic acid (DHA) is, in fact, effective for treating all human subjects exhibiting high levels of C-reactive protein and conditions that are characterized by elevation of C-reactive protein, in order to effect a reduction in the levels of C-reactive protein. Of this entire population of patients suffering from high levels of C-reactive protein, as well as the disease states that result from elevated C-reactive protein, Visser et al. provides the factual extrinsic evidence demonstrating that a subpopulation of such patients

suffering from high levels of C-reactive protein also suffer concomitantly from obesity. Accordingly, the suggestion of Phinney et al. to use the disclosed DHA-containing formulation for treating any patient exhibiting high levels of C-reactive protein and conditions that are characterized by elevation of C-reactive protein is a clear suggestion to use it in any subpopulation of patients with elevated C-reactive protein, such as those patients also suffering from obesity, with the reasonable expectation of the same (or at least substantially similar) level of efficacy in treating this subpopulation of patients as would be expected in the treatment of patients with elevated C-reactive protein *per se*. Moreover, as stated *supra*, since products of identical composition cannot have mutually exclusive properties when administered under identical conditions, or, as in the present case, the same host, whatever effect(s) the instantly claimed DHA composition has in decreasing the appetite of an obese or overweight mammal must reasonably be necessarily present in the method disclosed by Phinney et al. in view of Visser et al., absent factual evidence to the contrary. Please see MPEP §2112.

(2) As before, the allegation that Visser et al. fails to provide any teaching or suggestion as to how one of ordinary skill in the art would identify an obese or overweight mammal for treatment is factually incorrect. Contrary to Applicant's assertions, Visser et al., in fact, does teach that overweight or obese mammals can be identified using body mass index [BMI] (overweight: BMI of 25-29.9 kg/m^2 and obese: BMI of $\geq$ 30 kg/m^2), and who also discloses a threshold concentration of elevated CRP (i.e., $\geq$0.22 mg/dl; p.2132, col.2) to identify, of those overweight or obese patients, those with elevated CRP levels. Accordingly, this argument is unpersuasive, since it is clear that the teachings of Visser et al. clearly contradict Applicant's allegation.

Furthermore, in response to Applicant's consideration of the reference individually and not in combination as they were applied, Applicant is reminded that the cited references for the instant rejection are relied upon in combination and examining each of them separately, as Applicant has done, is tantamount to examining each of them inside of a vacuum. Applicant is also reminded that the claimed

invention is not required to be expressly suggested in its entirety by any one or all of the references cited under 35 U.S.C. 103(a). Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In view of such, arguments regarding the discrete teachings of each of the secondary references without considering the combination as a whole are not persuasive in establishing non-obviousness when the references, *as combined*, clearly dictate to the contrary.

For these reasons set forth *supra*, and those previously made of record at pages 7-11 of the Office Action dated June 29, 2007, rejection of claims 1-4, 6 and 30-32 remains proper and is **maintained**.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Phinney et al. (WO 03/043570; Published May 2003, Priority to November 2001) in view of Visser et al. ("Elevated C-Reactive Protein Levels in Overweight and Obese Adults", *Journal of the American Medical Association*,

1999; 282:2131-2135) and Bogentoft (WO 87/03198; 1987), in further view of The Merck Index (Monograph 792, p.121), each already of record.

Phinney et al. teaches formulations comprising a non-alpha tocopherol in combination with a highly unsaturated fatty acid, such as, e.g., all-cis, 4, 7, 10, 13, 16, 19-docosahexaenoic acid (DHA) (p.1, l.4-8 and p.4, l.16-19) , wherein the compounds may be used in a method for reducing one or more biochemical markers of inflammation, including, e.g., reducing C-reactive protein (p.3, l.33-p.4, l.15), particularly for treating conditions that are characterized by an elevation of, e.g., C-reactive protein (p.5, l.4-9). Phinney et al. further teaches that the DHA component may be in triglyceride form (p.11, l.30-35) and that the disclosed method may be used in mammalian subjects, such as, e.g., humans, farm animals etc. (p.13, l.27-28). Phinney et al. teaches formulations of the disclosed composition as medical foods and dietary supplements (p.23, l.10-14), which may further comprise vitamins, minerals, dietary substances to supplement the diet by increasing total dietary intake, etc. (p.23, l.19-25), and further teaches that the formulations may be administered orally (i.e., "enterally" as in instant claim 7; p.23, l.26-29), such as via capsules, tablets, pills, soft gel-caps, powders, solutions, dispersions or liquids (p.23, l.34-36). Exemplary dosage amounts of DHA, such as 10-10,000 mg, are disclosed at p.27, l.23-31.

Phinney et al. fails to teach decreasing the appetite of an obese or overweight mammal (claim 7), identifying an obese or overweight mammal (claim 7) or the concomitant use of a long chain n-6 polyunsaturated fatty acid (claim 7).

Visser et al. ("Elevated C-Reactive Protein Levels in Overweight and Obese Adults", *Journal of the American Medical Association*, 1999; 282:2131-2135) is cited for its teachings of elevated C-reactive protein (CRP; elevated CRP was considered to be $\geq$0.22 mg/dl; p.2132, col.2) among persons that were clinically overweight (body mass index [BMI] of 25-29.9 kg/m^2) or obese (BMI $\geq$ 30 kg/m^2) as compared to persons of normal weight (BMI <25 kg/m^2) in a study of 16,616, men and nonpregnant women aged 17 years (i.e., adolescent) or older (abstract). Visser et al. further teaches that higher BMI is associated with

higher levels of CRP, which suggests low-grade systemic inflammation in overweight and obese persons (abstract). Visser et al. further teaches that elevated CRP levels and obesity are known to be associated with the development of various prevalent diseases, including, e.g., rheumatoid arthritis, diabetes mellitus, and cardiovascular disease (para. bridging p.2133-2134).

In view of such teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention that the disclosed composition of Phinney et al. would have been reasonably expected to exert the same or substantially similar efficacy in the treatment of decreasing appetite in an overweight or obese mammal because: (1) the composition of Phinney et al. was known to have efficacy in reducing elevated levels of C-reactive protein in patients that suffer from such elevated levels and the disease states that are associated with elevated levels of C-reactive protein and (2) a proportion of patients with elevated C-reactive protein also suffer from concomitant obesity or overweight status. Phinney et al. provides the clear teaching that the disclosed formulation of a non-alpha tocopherol in combination with a highly unsaturated fatty acid, such as, eg., all-cis, 4, 7, 10, 13, 16, 19-docosahexaenoic acid (DHA) is, in fact, effective for treating all human subjects exhibiting high levels of C-reactive protein and conditions that are characterized by elevation of C-reactive protein, in order to effect a reduction in the levels of C-reactive protein, i.e., 100% of patients with elevated C-reactive protein, without exclusion. Of this entire population of patients suffering from high levels of C-reactive protein, as well as the disease states that result from elevated C-reactive protein, Visser et al. provides the factual extrinsic evidence demonstrating that a subpopulation of such patients suffering from high levels of C-reactive protein also suffer concomitantly from obesity. Accordingly, the suggestion of Phinney et al. to use the disclosed DHA-containing formulation for treating any patient exhibiting high levels of C-reactive protein and conditions that are characterized by elevation of C-reactive protein is a clear suggestion to use it in any subpopulation of patients with elevated C-reactive protein, such as those patients also suffering from obesity, with the reasonable expectation of the same (or at least substantially

similar) level of efficacy in treating this subpopulation of patients as would be expected in the treatment of patients with elevated C-reactive protein *per se*. Furthermore, since products of identical composition cannot have mutually exclusive properties when administered under identical conditions, or, as in the present case, the same host, whatever effect(s) the instantly claimed DHA composition has in decreasing the appetite of an obese or overweight mammal must reasonably be necessarily present in the method disclosed by Phinney et al. in view of Visser et al., absent factual evidence to the contrary. Please see MPEP §2112.

Moreover, one of ordinary skill in the art at the time of the invention would have found it *prima facie* obvious to use the guideline parameter of body mass index as disclosed in Visser et al. to (1) identify patients that were overweight or obese and demonstrated elevated C-reactive protein and (2) to treat those patients that are overweight or obese with the C-reactive protein biomarker reducing composition of Phinney et al., which contains a non-alpha tocopherol in combination with a highly unsaturated fatty acid, such as, *inter alia*, all-cis, 4, 7, 10, 13, 16, 19-docosahexaenoic acid (DHA) (p.1, l.4-8 and p.4, l.16-19), wherein the DHA component is administered in triglyceride form (p.11, l.30-35). Such a person would have been motivated to do so to (1) accurately identify obese patients with elevated C-reactive protein that would benefit from the CRP reducing composition of Phinney et al., (2) reduce and/or eliminate the low-grade inflammation associated with such elevated levels of C-reactive protein in such patients and (3) reduce the risk of developing other various diseases that are known to be associated with both obesity and elevated levels of C-reactive protein, such as, e.g., rheumatoid arthritis, diabetes mellitus and cardiovascular disease in such patients. The skilled artisan would have had a reasonable expectation of success in doing so because the prior art of Visser et al. acknowledged the clear association of elevated levels of CRP with obesity and the development of other serious inflammatory disorders.

Further, regarding the concomitant use of a long chain n-6 polyunsaturated fatty acid such as arachidonic acid (instant claims 7-8), Bogentoft teaches a method for weight reduction by orally administering an effective weight reducing dosage of a hydrophobic substance in the form of an enteric preparation (p.5, second full para.) for the treatment of obesity (p.1, l.1-3), wherein the hydrophobic substance is a fatty acid having 6-28 carbon atoms (p.3, second full para.), e.g., linolenic acid or linoleic acid (p.3, l.8-11), wherein the one or more fatty acids is in the form of a triglyceride (p.6, first full para.), and is administered 2-5 hours before each meal, from 1-6 times per day (p.5, last full para.), and wherein the preparation may be used for an overweight subject (p.2, last full para.). Bogentoft additionally teaches the use of animal fats (i.e., "mixtures of esters of fatty acids of 6-28 carbon atoms and glycerol"; see para. bridging p.3-4) in mixtures with the fatty acids.

The Merck Index is cited to show that arachidonic acid (i.e., the long-chain n-6 polyunsaturated fatty acid as in instant claims 7-8) was known in the art to be the major constituent of animal depot fats (see Monograph 792, p.121).

One of ordinary skill in the art would have been motivated to combine the pharmaceutical composition of Phinney et al., which comprises a non-alpha tocopherol in combination with a highly unsaturated fatty acid, such as, e.g., all-cis, 4, 7, 10, 13, 16, 19-docosahexaenoic acid (DHA), with the fatty acid composition of Bogentoft (that further contains animal fats, which comprises arachidonic acid; see Bogentoft, p.3-4 and Merck, Monograph 792, p.121) because Visser et al. provides a clear teaching that a subpopulation of patients with elevated C-reactive protein also suffers concomitantly from obesity. In view of such teachings, the use of a multivalent therapy comprising an effective C-reactive protein reducing agent (i.e., in this case, the non-alpha tocopherol and highly unsaturated fatty acid, wherein the fatty acid may be DHA) in combination with an effective weight-reducing agent [i.e., in this case, the fatty acid composition of Bogentoft (that further contains animal fats, which comprises arachidonic acid; see Bogentoft, p.3-4 and Merck, Monograph 792, p.121)] would have been *prima facie* obvious to one of

ordinary skill in the art treating obese patients suffering from elevated C-reactive protein. Such a person would have been motivated to do so not only to provide the patient with an effective C-reactive protein reducing agent (i.e., a non-alpha tocopherol and highly unsaturated fatty acid, wherein the fatty acid may be DHA), but also to provide this particular subpopulation of patients that concomitantly suffer from excessive weight (i.e., overweight or obese patients) an effective pharmacologic means of weight reduction via using a known weight-reducing agent, such as the composition of Bogentoft. This is because it is generally *prima facie* obvious to use, in combination, two or more agents to treat multiple concurrent symptoms so as to thereby improve the patient's overall health.

Conclusion

Rejection of claims 1-11 and 30-32 is proper.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
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May 19, 2008

/Ardin Marschel/
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